February 26, 2004

William H. Smock
Executive Director
Aromatic Sulfonic Acids Association
1850 M. Street, NW
Suite 700
Washington, DC 20036

Dear Mr. Smock:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Benzenesulfonic Acid posted on the ChemRTK HPV Challenge Program Web site on October 17, 2003. I commend the Aromatic Sulfonic Acids Association for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Association advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Benzenesulfonic Acid

Summary of EPA Comments

The sponsor, the Aromatic Sulfonic Acids Association, submitted a test plan and robust summaries to EPA for benzenesulfonic acid, CAS No. 98-11-3 dated September 16, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on October 17, 2003. Information was also provided for the analog *p*-toluenesulfonic acid, CAS No. 105-15-4.

EPA has reviewed this submission and has reached the following conclusions:

1. Analog Justification. EPA agrees with the submitter's choice of analog for the health effects endpoints.

2. Physicochemical Properties. The submitted data for all endpoints are adequate for the purposes of the HPV Challenge Program, except for vapor pressure. The submitter needs to provide measured vapor pressure for this chemical.

3. Environmental Fate. The submitted data for all endpoints are adequate for the purposes of the HPV Challenge Program.

4. Health Effects. The submitted data for the acute and genetic toxicity endpoints are adequate for the purposes of the HPV Challenge Program. Although the submitter has proposed conducting a combined screening test to address repeated-dose, reproductive and developmental endpoints, based on the strong acidic and corrosive nature of the substance, EPA believes that the sponsor needs to consider whether the proposed testing would yield meaningful results.

5. Ecological Effects. EPA agrees that available fish toxicity data are adequate and that aquatic invertebrate testing is appropriate; however, testing is also needed for algae.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Benzenesulfonic Acid Challenge Submission

Analog Justification

EPA agrees with the selection of *p*-toluenesulfonic acid as an analog for the health and ecological effects endpoints.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The submitted data for all endpoints are adequate for the purposes of the HPV Challenge Program, except for vapor pressure.

Vapor pressure. The test plan provided an estimated vapor pressure of 2.28×10^{-5} hPa (25 °C) for benzenesulfonic acid derived from EPIWIN (2001) and a calculated vapor pressure value of 3.9×10^{-6} hPa (25 °C) for the analog *p*-toluenesulfonic acid. According to OECD TG 104, because the estimated data indicate that the vapor pressures for benzene- and *p*-toluenesulfonic acids are above the testing threshold

value of $1x10^{-5}$ Pa, estimated values are not adequate for the endpoint; therefore, measured data are needed.

Environmental fate (photodegradation, stability in water, biodegradation, fugacity)

The submitted data for all endpoints are adequate for the purposes of the HPV Challenge Program.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The submitted data for the acute and genetic toxicity endpoints are adequate for the purposes of the HPV Challenge Program. Although the submitter has proposed conducting a combined screening test to address repeated-dose, reproductive and developmental endpoints, based on the strong acidic and corrosive nature of the substance, EPA believes that the sponsor needs to consider whether the proposed testing would yield meaningful results. Therefore, the submitter needs to reconsider the testing proposal before conducting such studies and better characterize the corrosivity with available in vitro methods.

Ecological Effects (fish, invertebrates, and algae)

The fish acute toxicity data for the analog *p*-toluenesulfonic acid, supported by QSAR model data, were adequate. EPA agrees with the submitter=s plan to test invertebrates since the existing information is deficient. However, EPA disagrees with the submitter=s proposal to make algal testing contingent on the results of the invertebrate test. Testing is needed for algae as an independent endpoint.

Specific Comments on the Robust Summaries

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

Stability in water. The submitter states in the test plan that no hydrolyzable groups are present in benzene- or *p*-toluenesulfonic acids. The information that arylsulfonic acids are not susceptible to hydrolysis should be provided in the robust summary for this endpoint.

Health Effects

Acute toxicity. The study for benzenesulfonic acid did not include the doses used, and clinical signs and mortality per dose level. The acute study for the analog, *p*-toluenesulfonic acid, did not describe the clinical signs according to dose.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.